

EXHIBIT 12

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS

3 DePuy Mitek, Inc., a
4 Massachusetts Corporation,

5 Plaintiff,

6 vs.

7 CIVIL ACTION
8 NO. 04-12457 PBS

9 Arthrex, Inc., a Delaware
10 Corporation,

11 Defendant.

12 DEPOSITION OF:

13 DONALD GRAFTON

14 DATE:

15 March 14, 2006

16 TIME:

17 8:38 a.m. to 1:23 p.m.

18 LOCATION:

19 The Ritz Carlton Golf Resort
20 2600 Tipuron Drive
21 Naples, FL 34112

22 TAKEN BY:

23 Plaintiff

24 REPORTER:

25 Deborah A. Krotz, RPR, CRR

 VIDEOGRAPHER:

 Gene Howell, CLVS

<p>1 Q. No?</p> <p>2 A. Not initially.</p> <p>3 Q. Okay. What suture was that?</p> <p>4 A. I don't recall the name of it.</p> <p>5 Q. You don't recall the name?</p> <p>6 A. No. It was a secondary company.</p> <p>7 Q. It was a 100 percent polyester suture?</p> <p>8 A. Yes.</p> <p>9 Q. Non-absorbable?</p> <p>10 A. Correct.</p> <p>11 Q. Was that a braided suture?</p> <p>12 A. Yes.</p> <p>13 Q. Did it have a core?</p> <p>14 A. I -- We didn't design it. We purchased it as an OEM, so I can't tell you that.</p> <p>15 Q. And was that suture sold attached to anchors?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay. Do you know what sizes?</p> <p>18 A. Size 2.</p> <p>19 Q. Size 2? Any other sizes other than Size 2?</p> <p>20 A. No.</p> <p>21 Q. Were you involved in the selection of this suture?</p> <p>22 A. Yes.</p> <p>23 Q. And did you say you can't remember the name of</p>	<p>14</p> <p>1 A. Well, I was engineer on the project. As far as 2 the specific involvement, it's been too long for me to 3 remember.</p> <p>4 Q. You were involved in reviewing various sutures 5 and selecting the one that Arthrex would purchase?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And this is for the suture or for the 8 company out of New Mexico?</p> <p>9 A. Yes.</p> <p>10 Q. And did you analyze various sutures?</p> <p>11 A. I don't remember.</p> <p>12 Q. You don't remember?</p> <p>13 A. No.</p> <p>14 Q. Do you remember if you looked at sutures from 15 other companies and picked this one from New Mexico as the 16 best or --</p> <p>17 A. I remember there was very little ability to 18 select the preferable suture because of a competitive 19 standpoint. The sutures were not available.</p> <p>20 Q. What do you mean by not available?</p> <p>21 A. J & J or Ethicon wasn't going to sell Arthrex 22 suture, so that eliminated that as a potential suture.</p> <p>23 Q. And there weren't many other sources, is that 24 what you're saying, other than J & J?</p> <p>25 A. That's what I'm saying.</p>
<p>1 the suture?</p> <p>2 A. That's correct.</p> <p>3 Q. What products was it sold on?</p> <p>4 A. Suture anchors.</p> <p>5 Q. Do you know the names of the products?</p> <p>6 A. All of the Arthrex suture anchors that were 7 available at that time.</p> <p>8 Q. Okay. Eventually, was this suture replaced?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And what was it replaced with?</p> <p>11 A. With a Pearsalls suture -- polyester suture.</p> <p>12 Q. 100 percent polyester suture?</p> <p>13 A. To my understanding, that's correct.</p> <p>14 Q. Was that a braided suture?</p> <p>15 A. Yes.</p> <p>16 Q. Did that suture have a trade name, that one for 17 Pearsalls, the polyester one?</p> <p>18 A. Yes.</p> <p>19 Q. What was the trade name of the --</p> <p>20 A. I don't remember.</p> <p>21 Q. Did the polyester suture from Pearsalls have a 22 core?</p> <p>23 A. I have no idea.</p> <p>24 Q. What was your involvement in the selection of the 25 first suture for Arthrex?</p>	<p>15</p> <p>17</p> <p>1 Q. Okay. How did --</p> <p>2 A. I didn't -- Excuse me. Did you say many other or 3 any other?</p> <p>4 Q. Many. Many other.</p> <p>5 A. There were others, but they -- they were not 6 used.</p> <p>7 Q. Were they examined or considered?</p> <p>8 A. I don't remember. I don't remember. You're 9 talking about a long time ago and a short period of time 10 that the manufacturer in New Mexico was used.</p> <p>11 Let me say this: The suture was changed from the 12 New Mexico company to Pearsalls because of the bioburden 13 levels on the suture was too high, and it was -- we had 14 trouble sterilizing it. And it was for a brief period of 15 time that that suture was used.</p> <p>16 So other than that, I can't give you any details.</p> <p>17 So if you want to pursue it, you can ask me what you want, 18 but I don't know that much about it because we didn't use 19 it that long, and we swapped because the suture was poor 20 when it come to being able to sterilize it.</p> <p>21 Q. How did -- What was your involvement with 22 selecting -- selecting the polyester suture from Pearsalls 23 as a replacement for this first suture?</p> <p>24 A. Another company that made suture that we had 25 located.</p>

<p>1 Q. And you don't recall whether or not the polyester 2 suture from Arthrex had a core?</p> <p>3 A. You said from Arthrex. You're talking about 4 Pearsalls now?</p> <p>5 Q. I'm sorry. The 100 percent polyester suture from 6 Pearsalls, did it have a core?</p> <p>7 A. Don't know.</p> <p>8 Q. Don't know? And the polyester that was braided 9 in the polyester suture from Pearsalls, do you know what 10 type of polyester that was?</p> <p>11 A. No.</p> <p>12 Q. When's the first time that you went over to 13 England to visit Pearsalls?</p> <p>14 A. Don't remember.</p> <p>15 Q. How many times have you been over to England to 16 visit Pearsalls?</p> <p>17 A. Three to five.</p> <p>18 Q. When you were involved in the process of 19 selecting this polyester suture from Pearsalls, did you go 20 over and visit Pearsalls?</p> <p>21 A. No.</p> <p>22 Q. No? At some point, Arthrex -- Let me back up. 23 What was the next suture that you can remember 24 Arthrex selling after the polyester?</p> <p>25 A. Jenzyme Tevdek.</p>	<p>22</p> <p>1 Q. Knot tiedown? Is that one of the considerations?</p> <p>2 A. Knot -- knot strength.</p> <p>3 Q. Was knot tiedown one of the considerations 4 that --</p> <p>5 A. Well, obviously, if you are going to tie a knot, 6 I mean, it's going to be tied down to something. Yes. 7 The makeup of the suture anchor, so, yes.</p> <p>8 Q. So the answer is yes?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. When you were selecting the Pearsalls 11 suture, was knot strength a consideration?</p> <p>12 A. Of course.</p> <p>13 Q. And when you were selecting the Pearsalls suture, 14 was tensile strength a consideration?</p> <p>15 A. Yes.</p> <p>16 Q. When you were selecting the Pearsalls suture, was 17 knot tiedown a consideration?</p> <p>18 A. Knot tiedown, knot strength are -- in my thinking 19 are similar or the same thing.</p> <p>20 Q. Same thing?</p> <p>21 A. (Witness nods head affirmatively).</p> <p>22 Q. What do you mean -- In your thinking, when you 23 say knot strength, what do you mean?</p> <p>24 A. Surgeon's application is to tie a knot. That is 25 affixing it to -- in approximation to tissue to bone.</p>
<p>1 Q. Were you involved in the selection of the Tevdek 2 suture?</p> <p>3 A. What do you mean involved? Primary 4 identification or selection or did I know the company? Or 5 you are going to have to -- When you say involved, sir, I 6 need to know exactly what you're talking about.</p> <p>7 Q. Okay. Were you involved in the selection of this 8 Tevdek suture from Jenzyme?</p> <p>9 MR. SOFFEN: Objection; vague. He just said he 10 doesn't have --</p> <p>11 A. I'm not sure -- Again, when you say involved, I'm 12 involved in this, but I'm not asking the questions. So 13 you need to -- when you say involved, what does involved 14 mean exactly? I -- I was the engineer that was 15 responsible for saying yes, this is a product that meets 16 engineering specifications.</p> <p>17 Q. Okay. Did you recommend that Arthrex sell the 18 Tevdek sutures?</p> <p>19 A. From an engineering standpoint, the material met 20 the specification or engineering requirements to be used 21 with a suture anchor.</p> <p>22 Q. And what were the engineering requirements that 23 you reviewed Tevdek suture for?</p> <p>24 A. Knot strength, tensile strength, color, 25 biocompatibility. You know. It's -- on and on.</p>	<p>23</p> <p>1 That is knot tiedown. And there's a knot placed in the 2 suture, so -- so tying a knot and knot tiedown are the 3 same things as far as I'm concerned.</p> <p>4 Q. Okay. You just said tying a knot and knot 5 tiedown is the same thing. My question was slightly 6 different. Knot strength versus -- What is your 7 understanding of knot strength?</p> <p>8 A. It's the mechanical tensile of the suture's 9 ability to -- to, after tying a knot, before breakage.</p> <p>10 Q. Did you generally consider knot strength to be 11 determined by tying a knot in a suture and testing it on a 12 tensile --</p> <p>13 A. Yes.</p> <p>14 Q. -- testing machine?</p> <p>15 A. Yes.</p> <p>16 Q. How about knot tiedown? Is that --</p> <p>17 A. We didn't test for knot tiedown.</p> <p>18 Q. So you -- Before, you said knot strength and knot 19 tiedown were the same thing.</p> <p>20 A. That's why I said that we tested for knot 21 strength -- okay -- for -- of tying a knot. And I 22 consider those the same things. So we didn't -- we didn't 23 test specifically for tying soft tissue down. We tested 24 the knot as tying a knot versus -- what the standard calls 25 for and doing a pull test on it.</p>

<p>1 different types of mandrels.</p> <p>2 Q. Okay.</p> <p>3 A. I'm not sure what you mean.</p> <p>4 Q. Something with a hook that the loop wraps around,</p> <p>5 goes around -- the suture loop goes around?</p> <p>6 A. I've got two hooks listed there, yes.</p> <p>7 Q. Okay. And you labeled the knot; right?</p> <p>8 A. Yes.</p> <p>9 Q. And this test is measuring -- Can you explain to</p> <p>10 me how this test is measuring --</p> <p>11 A. Yeah, once the crosshead moves --</p> <p>12 Q. Right.</p> <p>13 A. -- this is placed under a fixed tension to start</p> <p>14 with to remove any -- any slack in the loop --</p> <p>15 Q. Correct. Okay.</p> <p>16 A. -- and then once it's test -- once the crosshead</p> <p>17 is moved, you measure the tensile strength which is</p> <p>18 required to increase that loop opening.</p> <p>19 Q. Are you pulling on one of the parts of the knot?</p> <p>20 A. That's what -- What do you mean parts of the</p> <p>21 knot? No. The knot's here on the side. Pulling 90</p> <p>22 degrees from the knot on both ends.</p> <p>23 Here, I'll draw you a bigger picture.</p> <p>24 Q. Thank you.</p> <p>25 A. (Witness complying).</p>	<p>34</p> <p>1 that for knot security?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. So in selecting sutures in your</p> <p>4 experience, knot security, knot strength, tensile strength</p> <p>5 are all important considerations?</p> <p>6 A. Yes.</p> <p>7 MR. SOFFEN: Are you going to label that as an</p> <p>8 exhibit?</p> <p>9 MR. BONELLA: Sure. If you would date that and</p> <p>10 initial that, Mr. Grafton.</p> <p>11 We'll mark that as DePuy Mitek Exhibit 421. And</p> <p>12 that's Mr. Grafton's drawing of the knot security</p> <p>13 test.</p> <p>14 (DePuy Mitek Exhibit No. 421, Mr. Grafton's</p> <p>15 drawing of the knot security test, was marked for</p> <p>16 identification.)</p> <p>17 Q. The Tevdek suture, was that also polyester?</p> <p>18 A. Yes.</p> <p>19 Q. And Size 2?</p> <p>20 A. Yes.</p> <p>21 Q. Any other sizes?</p> <p>22 A. Possibly.</p> <p>23 Q. But you don't remember?</p> <p>24 A. No.</p> <p>25 Q. Was the Tevdek suture braided?</p>
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<p>1 Q. Well, the knot that you're describing here, is</p> <p>2 this knot the same knot as, for example, that you would</p> <p>3 tie your shoe? You just go over?</p> <p>4 A. It's a square knot.</p> <p>5 Q. You're calling it a square knot? Okay.</p> <p>6 A. Yes. Now you can tie many different knots there.</p> <p>7 Q. Right.</p> <p>8 A. To determine which knot has the best efficiency</p> <p>9 with use with that particular type of suture -- there's 30</p> <p>10 or 40 different types of knots.</p> <p>11 Q. Okay.</p> <p>12 A. The test calls for a square knot.</p> <p>13 Q. Okay. And when the force is applied, it's</p> <p>14 measuring -- you want it -- the object here is to</p> <p>15 determine how much -- or I'm sorry -- the object is to</p> <p>16 determine when the suture that's tied in this knot starts</p> <p>17 slipping out of the knot?</p> <p>18 A. Yes.</p> <p>19 Q. And the force at which it does that is considered</p> <p>20 the knot -- it's the knot security?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Did you analyze the Pearsalls polyester</p> <p>23 suture for knot security?</p> <p>24 A. Yes.</p> <p>25 Q. How about the Tevdek suture? Did you analyze</p>	<p>35</p> <p>1 A. Yes.</p> <p>2 Q. Did the Tevdek suture have a core?</p> <p>3 A. I have no idea.</p> <p>4 Q. Why was there a shift -- Let me back up. When</p> <p>5 Arthrex began selling the Tevdek polyester suture, did it</p> <p>6 stop selling the Pearsalls polyester suture?</p> <p>7 A. Yes.</p> <p>8 Q. Why was there a shift from the Pearsalls</p> <p>9 polyester suture to the Tevdek polyester suture?</p> <p>10 A. I answered that question already.</p> <p>11 Q. You did? I'm sorry. I missed it. What was the</p> <p>12 reason?</p> <p>13 A. The stiffness and compliance of the suture.</p> <p>14 Q. So the Tevdek suture was more compliant --</p> <p>15 A. That's correct.</p> <p>16 Q. Let me finish the question. The Tevdek suture</p> <p>17 was more compliant than the Pearsalls polyester suture?</p> <p>18 A. That's correct.</p> <p>19 Q. Did the Tevdek suture have a coating?</p> <p>20 A. Yes.</p> <p>21 Q. Do you know what the coating was?</p> <p>22 A. No.</p> <p>23 Q. And the Pearsalls suture, was the braid</p> <p>24 constructed on a carrier braider machine?</p> <p>25 A. Yes.</p>
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<p>1 A. What's the date on this?</p> <p>2 Q. The date on this is -- the last page is dated</p> <p>3 November 4th, 2005.</p> <p>4 A. Okay. I want to quantify this then, because</p> <p>5 you're talking about a time period after I worked for the</p> <p>6 company, so when you -- when it says in here that I'm</p> <p>7 familiar with these products, it would be at the time I</p> <p>8 had left the company. And this is -- this was written</p> <p>9 after I left the company. So I can't totally say that I</p> <p>10 am familiar with those products under that.</p> <p>11 Q. So you would agree that you were familiar with</p> <p>12 the state-of-the-art for surgical suture products as of</p> <p>13 the date you left Arthrex?</p> <p>14 A. Define state-of-the-art, sir.</p> <p>15 Q. State-of-the-art? Well, the general -- You don't</p> <p>16 have an understanding of what that means?</p> <p>17 A. I want to understand what you mean in the context</p> <p>18 of this state-of-the-art.</p> <p>19 Q. Okay.</p> <p>20 A. I mean there's -- there's -- there's --</p> <p>21 Q. This is from Pearsalls, so I can't tell you</p> <p>22 exactly what they mean, so ... Let me back up. When you</p> <p>23 were --</p> <p>24 A. I was -- I was familiar with the competitive</p> <p>25 products on the market and what we offered and how they</p>	<p>42</p> <p>1 and tensile strength; right?</p> <p>2 A. Yes.</p> <p>3 Q. Didn't that come up in your testing?</p> <p>4 A. I don't recall.</p> <p>5 Q. What was your involvement in the development of</p> <p>6 FiberWire?</p> <p>7 A. It was my idea.</p> <p>8 Q. When you say it was your idea, what do you mean</p> <p>9 by that?</p> <p>10 A. I'll give you -- Would you like the story on how</p> <p>11 FiberWire came about?</p> <p>12 Q. Sure.</p> <p>13 A. We were having issues from customers with the</p> <p>14 Tevdek suture being low tensile strength as compared to</p> <p>15 competitors' suture anchors with suture, primarily</p> <p>16 Ethicon.</p> <p>17 Q. Ethibond?</p> <p>18 A. Ethibond. This was numerous complaints from</p> <p>19 friendly surgeons, not -- not a massive amount of</p> <p>20 complaints, but it was determined that the tensile</p> <p>21 strength of the suture was not as good as the Ethicon</p> <p>22 Ethibond suture.</p> <p>23 Q. When you say friendly, do you mean friendly to</p> <p>24 Arthrex?</p> <p>25 A. Yes. And I had gotten a phone call from a Dr.</p>
<p>1 compared to the competitive products.</p> <p>2 Q. Okay. And that was as of the date you left</p> <p>3 Arthrex?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And how long were you familiar with</p> <p>6 Arthrex's suture products and the competitive suture</p> <p>7 products that are in the marketplace?</p> <p>8 A. When we started marketing the product, the</p> <p>9 sutures, until the time I left.</p> <p>10 Q. Okay. So sometime when Arthrex began selling the</p> <p>11 suture from the supplier from New Mexico?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. When Arthrex shifted from the Pearsalls</p> <p>14 suture to the Tevdek suture, was there any consideration</p> <p>15 to -- or for Arthrex designing its own suture?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Because we could find a suture OEM that was</p> <p>19 available already. Why manufacture the suture when</p> <p>20 there's a readily available source?</p> <p>21 Q. Now you said you tested for the Tevdek suture</p> <p>22 before it was selected; right?</p> <p>23 A. Of course.</p> <p>24 Q. And then it came back after it was selected, the</p> <p>25 response from surgeons was that it had low knot strength</p>	<p>43</p> <p>1 Deberdino who was a surgeon at Fort Sam Houston, San</p> <p>2 Antonio. His -- his comments were that he had tied three</p> <p>3 knots the previous afternoon using the FASTak product of</p> <p>4 Arthrex -- that's a glenoid labrum device -- and had broke</p> <p>5 the knots on all three of them. And -- you know -- he</p> <p>6 said it kind of jokingly. He said, "And I didn't even</p> <p>7 work out the day before."</p> <p>8 And so he was tying to be nice about it, but</p> <p>9 bottom line was your suture sucks. Okay?</p> <p>10 And so -- you know -- we're in a position where</p> <p>11 we need to find a suture that will be competitive. I had</p> <p>12 been to Pearsalls many times working on bioabsorbable</p> <p>13 products. This was the time that you referred to earlier</p> <p>14 where I said three to five, and was familiar with suture</p> <p>15 manufacturing, the steps required to manufacture a suture.</p> <p>16 One of the trips there, Mr. Lyon had pointed out</p> <p>17 to me a -- the other products they manufactured, which was</p> <p>18 fishing line and silk used in decorated drapes. The</p> <p>19 fishing line used a ultra-high molecular weight</p> <p>20 polyethylene material that was very strong, and I -- at</p> <p>21 some point, it was decided that we would try some of that</p> <p>22 for a suture.</p> <p>23 I had Pearsalls, mainly through Brian, as being</p> <p>24 the manufacturing person --</p> <p>25 Q. Brian Hallett?</p> <p>45</p>

<p>1 A. That's correct -- make some Size 2 braided 2 material, send to me, and at the -- coincidentally, at the 3 same time, I had a Dr. Steve Burkhardt from San Antonio and 4 a Dr. Casey Chan, who is a R & D guy in knot testing and 5 suture. They were -- they were at Arthrex at the time 6 when this material showed up.</p> <p>7 We tested the material. The strength was 8 excellent. The knot slippage was very poor, would not 9 hold a knot.</p> <p>10 So at that point in time, it looked like we would 11 not be able to use an alternative material of ultra-high 12 molecular weight polyethylene because the slippage of the 13 material -- because of the slippage of the material tested 14 with Casey Chan -- Dr. Chan and Dr. Burkhardt. And so at 15 that point in time, the -- the product was -- was on hold.</p> <p>16 I was on a trip to Chicago to the national sales 17 meeting, and I had this idea of adding PET to the 18 ultra-high molecular weight polyethylene to enhance the or 19 reduce the knot slippage of the product. I sent an e-mail 20 to Dr. Steve Burkhardt and suggesting that since he was 21 familiar with the testing we had done very recently with 22 just the ultra-high molecular weight PE, of adding the 23 PET, and his -- I'll never forget the e-mail. He thought 24 that was a killer idea.</p> <p>25 And so I had asked then at that time for Brian</p>	<p>46</p> <p>1 processed to make a braid.</p> <p>2 Q. Okay. And how many times were you over in 3 England?</p> <p>4 A. I told you already. Three to five.</p> <p>5 Q. Three to five.</p> <p>6 A. Approximate.</p> <p>7 Q. Is that total lifetime?</p> <p>8 A. That's an approximate number total lifetime, yes.</p> <p>9 Q. Have you been to other manufacturing facilities 10 for sutures?</p> <p>11 A. Jenzyme Tevdek.</p> <p>12 Q. And how many times have you been there?</p> <p>13 A. Once, I believe.</p> <p>14 Q. And when you were at Jenzyme Tevdek, did you see 15 the manufacturing processes for Tevdek?</p> <p>16 A. It was a dog and pony quick courtesy through the 17 facility.</p> <p>18 Q. So when you came up with the idea for using 19 ultra-high molecular weight polyethylene in a suture, did 20 you -- you say you are familiar with how sutures are made?</p> <p>21 A. I'm also a fisherman. There's -- you know -- 22 fishing line is -- uses ultra-high molecular weight 23 polyethylene as a material that's used for sport fishing, 24 very high strength.</p> <p>25 Pearsalls made fishing line. And so they had</p>
<p>47</p> <p>1 Hallett to make me samples up of using those two materials 2 and -- and send to me. And we tested the materials, and 3 now we had a product that had superior tensile strength 4 and greater knot strength than any competitive product out 5 on the market.</p> <p>6 Q. Okay. If I could just back up to a couple of 7 points that you mentioned to make sure I understand what 8 happened here. The -- You said the idea began -- or I'm 9 sorry. Back up. You said when this idea came up, you had 10 already been to Pearsalls several times?</p> <p>11 A. Mmm-hmm (affirmative).</p> <p>12 Q. And you were familiar with --</p> <p>13 A. Yes.</p> <p>14 Q. And when this idea came up, you were familiar 15 with how sutures were manufactured?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And what did you mean by that?</p> <p>18 A. One of the products -- projects that I worked on 19 was a bioabsorbable suture similar to what Ethicon sells 20 as Panacryl, and the difference being this was 100 percent 21 PLLA material. The -- so we worked on this for about a 22 year -- I don't know the exact time -- with many trips 23 over to Pearsalls to change the construct of the yarn to 24 enhance the tensile properties of the material. And so at 25 that time, I became familiar with how a suture is</p>	<p>49</p> <p>1 this material already available as a fishing line. So it 2 was an easy conversion -- you know -- conclusion, 3 conversion to say what if this is used as a suture 4 material, because ultra-high molecular weight polyethylene 5 is a totally inert material.</p> <p>6 Q. When you saw that Pearsalls had been using 7 ultra-high molecular weight polyethylene in fishing 8 line --</p> <p>9 A. Yes.</p> <p>10 Q. -- do you know how it was being used in fishing 11 line, what the construction was?</p> <p>12 A. No.</p> <p>13 Q. Was it a braided construction? Was it --</p> <p>14 A. I can't tell you for sure, sir.</p> <p>15 Q. You don't know?</p> <p>16 A. I wasn't interested in buying fishing line, so I 17 didn't look at the details of it.</p> <p>18 Q. So you had -- Sitting here today, you can't tell 19 me anything at all about how the fishing line that 20 Pearsalls was making with ultra-high molecular weight 21 polyethylene was constructed?</p> <p>22 A. It went through their manufacturing processes in 23 their company, but specifically how it was made, the 24 constructs, I have no idea or the size.</p> <p>25 Q. In other words, you have no idea if it was all</p>

<p>1 ultra-high molecular weight polyethylene or if it was 2 braided or -- 3 A. It's been too long ago. I can't tell you that. 4 Q. And your idea was to use the ultra-high molecular 5 weight polyethylene as a suture? 6 A. Yes. 7 Q. Okay. And you had Mr. Hallett make a Size 2, I 8 think you said? 9 A. Yes. 10 Q. Okay. Can you describe the construction of that 11 first -- 12 A. I don't remember now. It's been too long. 13 Q. Was it all ultra -- ultra-high molecular weight 14 polyethylene? 15 A. Initially, yes, as a test prototype material. 16 Q. Was it braided? 17 A. Yes. 18 Q. Was it an eight-carrier or a sixteen-carrier? 19 A. I don't remember. 20 Q. You said it was a Size 2 though? 21 A. Yes. 22 Q. So it was a Size 2 ultra-high molecular weight 23 polyethylene braided suture that did not have PET? 24 A. For the initial prototype material, that's 25 correct.</p>	<p>50 1 Q. Knot security test? 2 A. Yes. 3 Q. Was that the test we drew in Exhibit Number 421? 4 A. That's correct. 5 Q. Okay. And you said the strength was excellent, I 6 believe, of the initial prototype, but the knot slippage 7 was poor; is that right? 8 A. Yes. 9 Q. Okay. When you say the slippage was poor of the 10 initial prototype, what do you mean? 11 A. Less than the tensile strength capability of the 12 existing Arthrex product. 13 Q. So the knot slippage was less than the Tevdek 14 suture? 15 A. Yes. 16 Q. And it was -- knot slippage was such that it was 17 determined that the 100 percent ultra-high molecular 18 weight polyethylene suture prototype wasn't suitable to be 19 developed? 20 A. That's correct. Yes. 21 Q. Okay. Ultra-high molecular weight polyethylene, 22 you said the knot slippage was poor? 23 A. (Witness nods head affirmatively). 24 Q. Ultra-high molecular weight polyethylene, is that 25 a lubricious material?</p>
<p>1 Q. Okay. And it didn't have nylon or any other 2 material braided with it? 3 A. No. 4 Q. So the initial prototype was a ultra-high 5 molecular weight polyethylene braided suture prototype, if 6 you will? 7 A. Yes. Size 2. 8 Q. Size 2. And was the initial prototype, was it 9 coated? 10 A. I don't remember. 11 Q. Okay. Do you know if the initial prototype went 12 through any other manufacturing process like stretching or 13 heating, twisting? 14 A. I don't recall. 15 Q. Was the initial prototype 100 percent ultra-high 16 molecular weight polyethylene? 17 A. For the fourth time, yes. 18 Q. Okay. And you tested the initial prototype that 19 was 100 percent ultra-high molecular weight polyethylene 20 with Dr. Burkhart and Dr. Chen? 21 A. Dr. Casey Chen, correct. 22 Q. Okay. And the test that you conducted with Dr. 23 Burkhart and Dr. Chen on the ultra-high molecular weight 24 polyethylene was a knot strength test? 25 A. Knot security.</p>	<p>51 1 A. Yes. 2 Q. And was the knot slippage of this ultra-high 3 molecular weight polyethylene poor security because of the 4 lubricity of polyethylene? 5 A. Yes. 6 Q. Yes? 7 A. Yes. 8 Q. So then you came up with the idea to braid PET 9 with the ultra-high molecular weight polyethylene to 10 reduce the knot slippage? 11 A. Yes. 12 Q. And when you say knot slippage, we're referring 13 to this knot security test? 14 A. Yes. 15 Q. So are we using the terms knot slippage and knot 16 security interchangeably here? 17 A. You are, yes. 18 Q. In your testimony? 19 A. Yes. 20 Q. So the knot security of the 100 percent 21 ultra-high molecular weight polyethylene was poor, the 22 prototype; right? 23 A. Yes. 24 Q. And your idea was to add the PET and to improve 25 the knot security?</p>

<p>1 MR. SOFFEN: Objection; asked and answered. 2 You've asked him the same thing multiple times. But 3 you can answer. 4 A. I've lost count, it's been so many times, but the 5 answer again is yes. 6 Q. Okay. And Dr. Burkhardt said that was a killer 7 idea? 8 A. What was a killer idea? 9 Q. The killer idea was that your idea of adding 10 PED -- PET -- I'm sorry. I'll rephrase that question. 11 Did Dr. Burkhardt say that your idea to braid PET 12 with the ultra-high molecular weight polyethylene to 13 improve knot security was a killer idea? 14 A. Yes. 15 Q. Okay. And then you said you had Pearsalls 16 manufacture a prototype that had PET and ultra-high 17 molecular weight polyethylene braided? 18 A. Yes. 19 Q. And you tested that prototype? 20 A. Yes. 21 Q. And you said that that prototype had good knot 22 strength? 23 A. Correct. 24 Q. And the prototype of PET braided with ultra-high 25 molecular weight polyethylene had good knot security?</p>	<p>54 1 Q. I'm talking about the -- 2 A. The second prototype with the PET? 3 Q. Correct. 4 A. Yes. 5 Q. The second prototype that had the coating on it? 6 A. Yes. 7 Q. And was that part of your initial idea, or was 8 that -- because I thought you said your initial idea was 9 to add the PET. Was it also to coat it, or was that 10 something that came later? 11 A. If you're going to market the product, it needs 12 the coating on it, sir. 13 Q. Okay. But the prototype that was manufactured 14 that you asked -- 15 A. Most likely, it was coated, because it needed to 16 be as the final product would be marketed. 17 Q. You said most likely. Do you remember or you 18 don't remember whether the prototype that had the PET and 19 the ultra-high molecular weight polyethylene was coated? 20 A. I can't tell you for sure that it was at that 21 prototype stage. 22 Q. Okay. Was this prototype that you had -- after 23 you tested the prototype with PET with ultra-high -- 24 A. Excuse me. I want to change that. 25 Q. Okay.</p>
<p>55 1 A. Yes. 2 Q. And the prototype of PET and ultra-high molecular 3 weight polyethylene braided together also had good tensile 4 strength? 5 A. Yes. 6 Q. And after you tested this second prototype, if 7 you will, of the PET braided with ultra-high molecular 8 weight polyethylene, was then the decision made to pursue 9 trying to commercially develop this idea? 10 A. Yes. 11 Q. Did you -- when you made -- Who made the decision 12 to go forward and try to commercialize this idea? 13 A. Myself and Reinhold, surgeons that we 14 collaborated with, marketing people. You know, it wasn't 15 just myself. 16 Q. Okay. Was this prototype that had the PET 17 braided with the ultra-high molecular weight polyethylene, 18 was it -- did it have a coating on it? 19 A. Yes. 20 Q. It did? 21 A. (Witness nods head affirmatively). 22 Q. And what was the coating? 23 A. I forgot the name. It's like an MED2174s. 24 Q. That was on the prototype? 25 A. Which prototype are you referring to now?</p>	<p>55 1 A. I never got samples of constructions from 2 Pearsalls without a coating unless I specifically asked 3 for it not to be coated. So there's a very high 4 probability that the suture came as -- the second 5 prototype -- as coated. 6 Q. That was standard for them to coat it, in other 7 words? 8 A. Yes. 9 Q. Okay. So the initial prototype that was 10 ultra-high molecular weight polyethylene, did you ask for 11 that not to be coated? 12 A. No. 13 Q. So chances are that that one was coated? 14 A. Quite possibly. 15 Q. After you tested the prototype of PET and 16 ultra-high molecular weight polyethylene braided together, 17 did you believe that it would then work as a suture? 18 A. Yes. 19 Q. Okay. Is there anything else you think you 20 needed to do in order to determine whether it would work 21 as a suture? 22 A. Yes. 23 Q. What did you need to do? 24 A. Biocompatibility toxicity testing, bioburden 25 levels, all the design control GNP items that need to be</p>

<p>1 decitex?</p> <p>2 A. No. No, I can't remember that.</p> <p>3 Q. Do you recall evaluating any samples that had</p> <p>4 Dyneema 400 denier or higher?</p> <p>5 A. No.</p> <p>6 Q. Do you think you did or you just don't recall?</p> <p>7 A. I received -- I'm sure I received the samples.</p> <p>8 What I did with them, I don't recall.</p> <p>9 Q. Okay. How long -- how much before this letter do</p> <p>10 you think you came up with the idea to use the ultra-high</p> <p>11 molecular weight polyethylene with PET blended together?</p> <p>12 A. Whatever the Chicago National Sales Meeting was.</p> <p>13 The flight just before the start date would be the time</p> <p>14 that I came up with the idea. I don't know what that time</p> <p>15 is. I just remember the circumstance.</p> <p>16 Q. You say Chicago National Sales Meeting?</p> <p>17 A. That's correct.</p> <p>18 Q. Is that Arthrex National Sales Meeting?</p> <p>19 A. Yes.</p> <p>20 Q. Was that a meeting with all the Arthrex sales</p> <p>21 reps.?</p> <p>22 A. That's correct.</p> <p>23 Q. And it was sometime before the July -- It was the</p> <p>24 meeting before the July 10, 19 -- I'm sorry. The meeting</p> <p>25 where you came up with the idea was the meeting before the</p>	<p>66</p> <p>1 A. Yes.</p> <p>2 Q. It's not like they had a product that they could</p> <p>3 just give to you?</p> <p>4 A. No.</p> <p>5 Q. In your letter, you say you tested the samples of</p> <p>6 Dyneema. Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And then you say, "Can you build a 25 percent</p> <p>9 Dyneema/75 percent polyester blend in Size 2 that is very</p> <p>10 flexible (like the existing suture or the Ethicon sample)</p> <p>11 and send it to me to test"; do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Does that Ethicon sample, does that refer to an</p> <p>14 Ethibond?</p> <p>15 A. Yes.</p> <p>16 Q. And you say, "If we get the" -- "If we can get</p> <p>17 this blend correct, we will have a terrific advancement in</p> <p>18 suture for our soft tissue anchors"; do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. What did you mean by that?</p> <p>21 MR. SOFFEN: Objection; vague. It states what it</p> <p>22 states. What's the question?</p> <p>23 Q. Do you understand the question?</p> <p>24 A. I'm not sure what -- what you're asking.</p> <p>25 Q. I would like to know what you mean by in your</p>
<p>1 July 10th, 1998 date on this letter?</p> <p>2 A. Yes.</p> <p>3 Q. I show you DePuy Mitek Exhibit 324. Do you</p> <p>4 recognize Exhibit 324 as a letter from you to Mr. Hallett?</p> <p>5 A. I don't recall the letter, but I recognize my</p> <p>6 name and the contact person. But the specific</p> <p>7 circumstances of the letter, I don't remember.</p> <p>8 Q. Based on your prior testimony, is it then true</p> <p>9 that this letter was after you came up with the idea and</p> <p>10 after you evaluated the prototype?</p> <p>11 A. Yes. After I came up with the idea, yes.</p> <p>12 Q. Okay. Was this letter sent before or after you</p> <p>13 came up with the -- I'm sorry. Was this November 16th,</p> <p>14 1998 letter sent before or after you came up with the --</p> <p>15 Sorry. I will rephrase the question.</p> <p>16 Was the November 16th, 1998 letter, Exhibit 324,</p> <p>17 sent before or after you evaluated the prototype of</p> <p>18 ultra-high molecular weight polyethylene braided with PET?</p> <p>19 A. I don't recall.</p> <p>20 Q. When you had the prototype of PET and ultra-high</p> <p>21 molecular weight polyethylene made, do you know if</p> <p>22 Pearsalls specifically made that or if they just pulled it</p> <p>23 off their line from something else?</p> <p>24 A. I'm sure they made it.</p> <p>25 Q. They specifically made it?</p>	<p>67</p> <p>1 letter when you said, "If we can get this blend correct."</p> <p>2 You asked them for a 25 percent Dyneema/75 percent</p> <p>3 polyester blend in Size 2 that's very flexible. And then</p> <p>4 you said, "If we can get this blend correct, we will have</p> <p>5 a terrific advancement."</p> <p>6 What did you mean by "If we can get this blend</p> <p>7 correct"?</p> <p>8 A. The optimization of the two materials. If you</p> <p>9 had the knot strength, loop security, and tensile</p> <p>10 strength, as well as the tactile feel of the suture all</p> <p>11 superior to what was on the market, then it would be a</p> <p>12 superior product.</p> <p>13 Q. Wait a second. You said optimization of two</p> <p>14 materials.</p> <p>15 A. (Witness nods head affirmatively).</p> <p>16 Q. At this point in time, November 1998, were you</p> <p>17 trying to vary the amount and type of the Dyneema and</p> <p>18 polyester in the braid in order to get the best</p> <p>19 properties?</p> <p>20 A. During -- during the -- during that period of</p> <p>21 time, yes.</p> <p>22 Q. So you were balancing off the properties of each</p> <p>23 material to try to get the optimum properties --</p> <p>24 A. Tensile strength.</p> <p>25 Q. To get the optimum tensile strength?</p>

<p>1 A. (Witness nods head affirmatively). 2 Q. What about knot security? 3 A. Yes. 4 Q. Okay. So you were varying the amount and type of 5 the materials to get the optimum knot security, optimum 6 tensile strength? 7 A. Yes. 8 Q. Any other properties? Knot tiedown? 9 A. The slideability of the knot, the tactile feel in 10 the surgeon's hands of the material. 11 Q. So you were varying type and proportion of the 12 materials to optimize all these properties in the product? 13 A. Yes. 14 Q. Were the product samples that were being made at 15 this time in November of 1998, around this time, were they 16 being made on a carrier braid machine? 17 A. Yes. 18 Q. I show you DePuy Mitek Exhibit 325. It's a 19 letter dated November 16th, 1998 from Mr. Hallett to you. 20 Do you see that? 21 A. Yes. 22 Q. Do you recall receiving this letter? 23 A. No. 24 Q. It says -- Mr. Hallett says in the letter, 25 "Please find enclosed a matrix of information of the</p>	<p>70 1 Q. Do you see under the yarns the first one is 2 Dyneema? 3 A. Yes. 4 Q. And is has a DT number. Do you see that? 5 A. DT. 6 Q. Dt-no. Does that stand for DT number? 7 A. Where -- where do you see DT? 8 Q. The second column. 9 A. At the top as the heading, yes. 10 Q. Okay. Are you familiar that Pearsalls uses the 11 terminology DT number for samples? 12 A. I don't recall what they use. 13 Q. You don't recall? Okay. 14 Was it the first sample -- Do you see where the 15 first one is Dyneema and the second ones are Polys, the 16 second through fourth are Poly/Dyneema? Do you see that? 17 A. Yes. 18 Q. Was the first sample of yarn here all Dyneema? 19 A. Evidently. 20 Q. Do you see in the second through the fourth yarns 21 were a braided blend of Polyethylene and Dyneema? 22 A. Yes. 23 Q. Do you see the straight pull column? 24 A. Yes. 25 Q. I'm sorry. I may have misspoke.</p>
<p>71 1 samples that you took with you on your visit to Pearsalls. 2 I will endeavor to proceed with the existing trial to 3 match the US2 Excel Braid made by Ethicon, in polyester 4 construction." Do you see that? 5 A. Yes. 6 Q. Did you pick up the samples from Pearsalls that 7 are mentioned in this -- 8 A. I don't recall. 9 Q. Do you recall whether they were actually -- Do 10 you recall going over to Pearsalls and having them 11 actually make samples while you were there? 12 A. Yes. 13 Q. And were these samples -- These aren't samples 14 they pulled off the line? These are samples where they 15 took yarns and braided them according to what you guys 16 were considering? 17 A. Repeat the question again. 18 Q. Sure. I'm just trying to get the sense of 19 whether the samples that you picked up while you were at 20 Pearsalls that you saw being made, were they -- was it an 21 existing product they were picking up off the product 22 line, or was this -- you know -- yarns that were selected 23 and braided and going through the manufacturing process 24 that you particularly picked out? 25 A. The latter.</p>	<p>73 1 The second through fourth yarns that are listed, 2 the Poly/Dyneema, is that -- are they Polyester and 3 Dyneema? 4 A. Yes. 5 Q. Not polyethylene and Dyneema? 6 A. It's ultra-high molecular weight polyethylene and 7 PET. 8 Q. Okay. Do you see the column straight pull? 9 A. Yes. 10 Q. Do you know what that means? 11 A. Testing that they did in their lab with their 12 tensile test machine in kilograms. 13 Q. Is that with a knot or without a knot? 14 A. That's without a knot. 15 Q. Okay. And do you see how the Dyneema one was 16 23.12 kilograms? 17 A. Yes. 18 Q. And Poly/Dyneemas were on the order of 34 to 36 19 kilograms? 20 A. Yes. 21 Q. Do you know why the difference in strength 22 between the Dyneema one and the other ones? 23 A. You can't tell by looking at this report why 24 there's a difference. 25 Q. And you don't remember?</p>

<p>1 A. No.</p> <p>2 Q. I show you DePuy Mitek Exhibit 54. Do you 3 recognize Exhibit 54?</p> <p>4 A. Yes.</p> <p>5 Q. Is this the Marketing Product Initiation 6 generated by you on September 28th, 2000?</p> <p>7 A. Correct.</p> <p>8 Q. Do you see where the description and intended use 9 has blended non-absorbable suture, 3.6:1 ratio using 10 Dyneema as core and polyester as the outside jacket?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Do you recall having an idea for using -- 13 making a suture that had Dyneema as a core and polyester 14 on the outside?</p> <p>15 A. As another prototype, yes.</p> <p>16 Q. Another prototype? Was this idea -- it was after 17 you had the idea of braiding the ultra-high molecular 18 weight polyethylene and the PET?</p> <p>19 A. No. This is a -- this is a general form used to 20 start a project. It's not a technical or a detailed form. 21 It just gives the conceptual idea of, again, what if, and 22 is it approved. It does not try to go into the detail on 23 what the constructions, quantity of constructions and 24 types would be. It's to get a project started only.</p> <p>25 Q. Okay. I just want to make sure I understand the</p>	<p>74</p> <p>1 product.</p> <p>2 Q. This Marketing Product Initiation form, was this 3 approved?</p> <p>4 A. There are signatures at the bottom, yes.</p> <p>5 Q. And what does the approval of the Marketing 6 Product Initiation form mean at Arthrex?</p> <p>7 A. It means that a project is going forward as a 8 marketable project officially.</p> <p>9 Q. Officially. So this idea officially started to 10 go forward, but then at some point stopped?</p> <p>11 A. No. This was the initial sheet to begin 12 marketing a FiberWire type of product, and this is a 13 conceptual sketch of -- of how it could be, but was not 14 what the product ended up being.</p> <p>15 Q. So did this Marketing Product Initiation form, 16 Exhibit 54, cover FiberWire whatever form it came out? Is 17 that what you are saying?</p> <p>18 A. Are you finished with your question?</p> <p>19 Q. Yes.</p> <p>20 A. Yes.</p> <p>21 Q. Who came up with the term "FiberWire"?</p> <p>22 A. The president and founder of Arthrex, Reinhold 23 Schmieding.</p> <p>24 Q. Were you present when he coined that term?</p> <p>25 A. I don't remember.</p>	<p>76</p>
<p>75</p> <p>1 timing sequence here because this -- this document refers 2 to a Dyneema as the core and polyester as the outside 3 jacket?</p> <p>4 A. Yes.</p> <p>5 Q. And before, I think you told me that you came up 6 with the idea of braiding PET with ultra-high molecular 7 weight polyethylene?</p> <p>8 A. Yes.</p> <p>9 Q. And that was what Dr. Burkhardt referred to as the 10 killer idea?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. I just wanted to make sure. I think it 13 was your testimony that idea was before this September 14 28th, 2000 date?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. So at some point, you started to evaluate 17 a Dyneema core surrounded by a polyester jacket?</p> <p>18 A. As one of the items; not all.</p> <p>19 Q. Okay. And do you recall evaluating that idea?</p> <p>20 A. No.</p> <p>21 Q. No?</p> <p>22 A. (Witness nods head negatively). It would be for 23 a very limited time.</p> <p>24 Q. Why do you say that?</p> <p>25 A. Because it wasn't -- we didn't come out with that</p>	<p>77</p> <p>1 Q. What was his involvement in the development of 2 FiberWire?</p> <p>3 A. Supportive and as president of the company to 4 approve products that would be marketed by the company -- 5 at company direction.</p> <p>6 Q. Do you know how he chose the term "FiberWire"?</p> <p>7 A. No.</p> <p>8 Q. You are familiar with FiberWire's construction; 9 right?</p> <p>10 A. Mmm-hmm (affirmative).</p> <p>11 Q. It's made up of different yarns that are braided 12 together in the core -- I'm sorry -- in the sheath?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And does fiber -- are those yarns made up 15 of -- the yarns that are braided in the sheath made up of 16 fibers?</p> <p>17 A. Filaments.</p> <p>18 Q. When you say "filaments," you're saying not 19 fibers? Is there a difference --</p> <p>20 A. I don't know. I'd have to look up the definition 21 of fiber to be able to tell you exactly what that says. 22 I'm calling it filaments.</p> <p>23 Q. Okay.</p> <p>24 A. That make up -- multiple filaments make up a 25 yarn. Multiple yarns are braided to make a final braid.</p>	<p>77</p>